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Serial No.: 10/810,956
Confirmation No.: 9825
Filed: March 26, 2004
For: THERMAL SURGICAL PROCEDURES AND COMPOSITIONS

Remarks

Telephone Interview

Applicants thank the Examiner for the telephone interview conducted on May 25, 2006. The arguments presented below summarize and clarify Applicants' arguments regarding the teachings of the applied references as discussed during that interview.

The 35 U.S.C. §103 Rejections

Claims 1 and 3-6 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lentz (U.S. Patent No. 6,231,536 B1) in view of Falk et al. ("Hyperthermia in oncology," *Int. J. Hyperthermia*, 2001;17(1):1-18). Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. See M.P.E.P. § 2143.

The proposed combination of *Lentz* and *Falk et al.* does not establish a *prima facie* case of obviousness with respect to claims 1 and 3-6, which recite methods that combine contacting biological material with an inflammation inducing composition *and* adjusting the temperature of the biological material.

The basis of the obviousness rejection is the assertion that *Lentz* teaches the administration of an inflammatory agent with ionizing radiation while *Falk et al.* teaches treatment methods that combine ionizing radiation with hyperthermia. It is asserted, therefore, that one of ordinary skill in the art would be motivated to administer an inflammatory agent in conjunction with hyperthermia in view of *Lentz* and *Falk et al.* As discussed below, however, *Lentz* does not teach or suggest treatments that combine administration of an inflammatory agent with ionizing radiation. Furthermore, *Falk et al.* does not remedy that basic deficiency of *Lentz*.

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As a result, a *prima facie* case of obviousness cannot be established on the basis of *Lentz* in view of *Falk et al.*

It is an object of *Lentz* "to provide a method and compositions that does [*sic*] not involve nonselective, extremely toxic, systemic chemotherapy." *Lentz*, col. 1, lines 65-67. The methods taught in *Lentz* involve treating cancer (and other conditions) by using ultrapheresis to stimulate a patient's immune system to attack solid tumors. That is, *Lentz* teaches a method of treating patients that includes the removal of soluble receptor inhibitors (e.g, sTNFR-1, sTNFR-2, sIL-2R, sIL-1R, sIL-6R, sIFN-gammaR) from the patient's blood to stimulate the patient's own immune system to attack solid tumors. See, e.g., *Lentz*, col. 2, lines 1-18.

Lentz additionally teaches that the ultrapheresis treatment may be "combined with an alternative therapy, for example, treatment with an anti-angiogenic compound, one or more cytokines such as TNF, gamma interferon, other interferons, or IL-2, or a procoagulant compound." *Lentz*, col. 2, lines 26-30. In other words, the ultrapheresis may be combined with administration of one of three different treatments (an anti-angiogenic compound, one or more cytokines, or a procoagulant compound).

As another alternative, *Lentz* also teaches that "[a]lternatively, the ultrapheresis treatment can be combined with local chemotherapy, systemic chemotherapy, and/or radiation." *Lentz*, col. 2, lines 37-39. In other words, *Lentz* teaches that ultrapheresis may alternatively be combined with chemotherapy (local or systemic) and/or radiation (in place of the other alternatives which include administering an anti-angiogenic compound, one or more cytokines, or a procoagulant compound).

It was noted during the telephone interview between Applicants' representative and the Examiner that the first paragraph of the Background section of *Lentz* does include the following disclosure:

The present invention is generally in the field of enhancing an immune response, and particularly relates to the removal of inhibitors of immune mediators, in combination with anti-angiogenic compounds, cytokines, compounds inducing a procoagulant state, chemotherapeutics and/or radiation.

Lentz, col. 1, lines 8-13

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On the basis of the above statement, it was asserted that *Lentz* does teach the administration of an inflammatory agent in conjunction with radiation. Applicants, however, respectfully disagree.

It must be noted that, in the section of *Lentz* reproduced above, the list of alternative treatments that may be combined with ultrapheresis includes commas between each of the alternative therapies while no comma is presented between the combination of "chemotherapeutics and/or radiation" which appears at the end of the list of alternatives. In other words, the passage of *Lentz* reproduced above teaches only that ultrapheresis may be combined with: 1) anti-angiogenic compounds, 2) cytokines, 3) compounds inducing a procoagulant state, 4) chemotherapeutics and/or radiation. This interpretation is, of course, in agreement with the more detailed disclosures provided in column 2 of *Lentz* (as discussed above).

This interpretation is also supported by division of the alternate therapies into groups in which only chemotherapeutic treatment is combined with ionizing radiation. See, e.g., *Lentz*, col. 5, lines 40-52. Further support for this interpretation of *Lentz* is also found in the examples presented in *Lentz* in which the three examples that include therapies administered in conjunction with ultrapheresis include only an anti-angiogenic compound (thalidomide). See, e.g., *Lentz*, col. 7-8.

In view of the above, any assertion that *Lentz* teaches the administration of an inflammatory agent in conjunction with ionizing radiation treatment cannot be maintained because *Lentz* actually teaches that ultrapheresis may be combined with administration of an inflammatory agent or ionizing radiation - not administration of an inflammatory agent in conjunction with ionizing radiation as asserted in the Office Action. This approach is consistent with the requirement that "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.02(VI), p. 2100-132, 8th Ed. Rev. 3 (August 2005) (emphasis in original) (citing *W.L. Gore*

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& Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)).

Applicants further submit that *Falk et al.* does not provide that which is missing from *Lentz* to support a case of *prima facie* obviousness with respect to claims 1 and 3-6.

Falk et al. provide an overview of the clinical application of hyperthermia (i.e., raising the temperature of tissue) with conventional treatment modalities. *Falk et al.*, Abstract. The conventional treatment modalities include radiation (e.g., ionizing radiation), chemotherapy, radiochemotherapy. *Falk et al.*, Abstract, and p. 2, item 2.1 to p. 3, item 2.3. None of the disclosed treatment modalities, however, teach or suggest contacting the biological material with an inflammation-inducing composition. Thus, *Falk et al.* does not provide that which is missing from *Lentz*.

For at least the reasons presented above, Applicants respectfully submit that a case of *prima facie* obviousness has not been established for claims 1 and 3-6 over *Lentz* in view of *Falk et al.* Reconsideration and withdrawal of the rejection of claims 1 and 3-6 are, therefore, respectfully requested.

Claim 2 was rejected under 35 U.S.C. §103(a) as being unpatentable over *Lentz* in view of *Falk et al.* and further in view of *Pettus* (U.S. Patent No. 5,722,985). Applicants respectfully traverse this rejection.

As discussed above, a *prima facie* case of obviousness has not been established for independent claim 1 (from which claim 2 depends) based on the combination of *Lentz* and *Falk et al.* Furthermore, the deficiencies in the asserted *prima facie* obviousness rejection of claim 1 based on *Lentz* and *Falk et al.* are not remedied by the addition of *Pettus*. Consequently, a *prima facie* case of obviousness has also not been established for claim 2.

Pettus teaches an instrument that provides stereotactic surgery, high energy beta brachytherapy, and aspiration administered from the center of a tumor. *Pettus*, col. 1, lines 22-26. While supplementary therapy may be provided, including, *inter alia*, cryotherapy and hyperthermia therapy, there is no teaching or suggestion in *Pettus* of contacting the biological

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material with a inflammation inducing composition. Thus, the deficiencies of *Lentz and Falk et al.* are not remedied by *Pettus*.

For at least the reasons presented above, Applicants respectfully submit that a case of *prima facie* obviousness has not been established for claim 2 over *Lentz* in view of *Falk et al.* and *Pettus*. Reconsideration and withdrawal of the rejection of claim 2 are, therefore, respectfully requested.

Summary

It is respectfully submitted that claims 1-6 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 30th day of August, 2006, at 2:45 pm (Central Time).

By: Name: Sue Dombroske
